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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,986	09/13/2006	Piero Del Soldato	026220-00061	6969

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EXAMINER	
CUTLIFF, YATE KAI RENE	

ART UNIT	PAPER NUMBER
1621	

NOTIFICATION DATE	DELIVERY MODE
02/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,986	DEL SOLDATO ET AL.	
	Examiner	Art Unit	
	YATE' K. CUTLIFF	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-26* is/are pending in the application.

4a) Of the above claim(s) *2 and 11-23* is/are withdrawn from consideration.

5)☒ Claim(s) *4,24 and 25* is/are allowed.

6)☒ Claim(s) *1,6 and 26* is/are rejected.

7)☒ Claim(s) *3 and 7-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1 – 4 and 6 - 26 are pending.

Claim 5 has been canceled

Claims 2 and 11-23 have been withdrawn.

Claims 1, 6 and 26 are rejected.

Claims 3, 7 - 10 are objected.

Claims 4, 24 and 25 are allowed.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2008 has been entered.

Specification

3. The disclosure is objected to because of the following informalities: on page 18 of the original specification, page 18 line 13 (Example 2A), the term synthesis is spelled as "Sinthesis".

Appropriate correction is required.

Response to Arguments

4. Applicant's arguments see pages 18 - 21, filed November 25, 2008, with respect to claims 1, 3, 4, 7-10 and 24-26 have been fully considered and are persuasive in view of the amendment to claim 1 and the arguments presented. The 35 U.S.C. 103(a) rejections of claims 1, 3, 4, 7-10 and 24-26 have been withdrawn. However, the 35 U.S.C. 103(a) rejection of claim 6, in view of Del Soldato et al. (US 5,861,426) is maintained for the reasons set forth in the Office Action mailed June 25, 2008 and the reasons set out below.

5. Applicant asserts that Y in the claims 1 and 6 that can be a number of definitions but Y is Br, Cl and I are not possible. However, as set out in claim 6, which depends upon claim 1, Y continues to be defined as Br, Cl and I.

6. Also, Applicant asserts that US'426 does not provide any examples or data regarding compounds obtained by the alternative reaction route. Applicant is reminded that it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly, teaches, when viewed in light of the admitted knowledge in the art to the person of ordinary in the art. In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). However, in this case, US'426 states that the alternative process can be used for products of Va and Vb of group V).

7. Lastly, Applicant submits that Examiner's rejection was based on hindsight. However, "any judgement on obviousness is in a sense necessarily a reconstruction

based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). In this instance, the process of US'426 was within the knowledge of the ordinary skilled artisan at the time of Applicant's claimed invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 6 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 identifies R as a radical of the pharmacologically active compound (V), however, there is no (V) identified in the claim.

11. Claim 6 recites the limitation "Y is selected from the group consisting of Br, Cl, I..." in line 2. There is insufficient antecedent basis for this limitation in the claim since claim 1, as amended does not include this definition for Y.

12. Claim 26 recites the limitation "...in the compound of formula (B), Y is "Br" in line 2. There is insufficient antecedent basis for this limitation in the claim 4. In claim 4 formula (B) is R-COOZ where R is defined by the claim and Z is H or a cation as set out in the claim.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

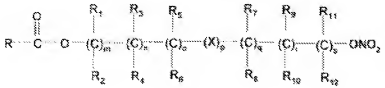
14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

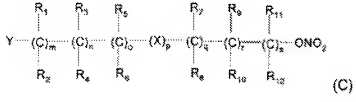
16. Claims 1 and 6 are rejected, in part, under 35 U.S.C. 103(a) as being unpatentable over Del Soldato 9US 5,861,426).

17. The rejected claims are drawn to the process for preparing a compound of general formula (A).



(A)

The substituents are defined by claim 1. The process comprising the reaction of a compound of formula (B) (R-COO-Z, with the compound of formula (C),



(C)

The substituents for Y are defined as Br, Cl or I in claim 6.

18. US'426, teaches in column 16 lines 3-14 an alternative process for forming the nitrooxyalkyl substituted esters of carbolylic acids which are pharmacologically active, by the reaction of sodium or potassium salts of the acids with nitric esters of halogen alcohols of the general formula:

$NO_2—O—Y—Cl\ (Br,I)$

to directly give the products of the invention.
The reaction route is as follows:

$R—CO—ONa+Br—Y—ONO_2 \rightarrow R—CO—O—Y—ONO_2$

wherein YO is X_1.

The synthetic scheme outlined by US'426 *generically embraces the instant process,* as well as teaching structurally similar compounds. The structurally similar compounds are correspondingly where R-CO-O-Na is instant compound of formula [B] and Br-Y-NO2 is instant compound of formula [C] and R-CO-O-Y- NO2 is compound of formula [A].

Applicant's process differs from the prior art in that the prior art is directed to a broader genus.

This difference would not have been patentable because it would have been obvious, at the time of that Applicants' invention was made, to one of ordinary skill in the art to have employed a method to prepare nitrooxyester compounds or derivatives thereof with the teachings of US'426; with a reasonable expectation that the sub-genus would have a utility of the genus as a whole.

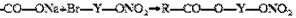
Allowable Subject Matter

19. Claims 4, 24 and 25 are allowed.

20. The following is a statement of reasons for the indication of allowable subject matter: Claim 4, the elected species, is a process for preparing the compound of formula (A) of the claim where R is defined as a ferulic acid radical of formula (XXXII). The process of claim 4 overlaps with the process of claim 1; however, the elected species where R is defined as a ferulic acid radical in the compound of formula (B), R-COOZ, is outside the compounds of formula (B) in the definitions for R of claim 1. Further, the substituent R as a ferulic acid radical of formula (XXXII) is not taught or suggested as a definition of R in the US'426, as such one of ordinary skill in the art,

when reviewing the below listed reaction process, in light of the varied definitions for R in US'426 would not have been motivated to use the ferulic acid radical of formula (XXXII) in the formula R-CO-ONa, of the reaction process set out below.

The reaction route is as follows:



wherein YO is X_1.

21. Claim 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph of claim 1, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

22. Claims 7-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph rejection of claim 1, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

23. Claim 6 is currently dependent on claims 1 or 4, however, when claim 6 is dependant solely on claim 4, it is allowable, however, at this time in addition to be rejected in part it is objected to for being dependent upon a rejected base claim 1 and would be allowed if rewritten to depend only from claim 4.

Art of Record

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 7,399,878 (Del Soldato).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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